| | | | Appli | cation Number | 10/643, | 673 | |
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| ANSMITTAL FORM | | | Filing | Date | August | August 19, 2003 | |
| m ⁽⁾ 以FORM | | First I | Named Inventor | Hyon et | al. | | |
| (to be used for all co | orrespondence after i | nitial filing) | Group | Art Unit | 3864 | | |
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| Total Number of Page | es in This Submission | · | Attorn | ey Docket Number | 1736-00 | 00001/REC | |
| | | ENCL | OSURES | (check all that apply) | | | |
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| Extension of Time Request Powe Change | | Power Chang | r of Attorney, Revocation ge of Correspondence Address | | | er Enclosure(s) se identify below): | |
| Express Abandor | rment Request | Termin | nal Disclaimer | | F | orm 1449; Return postcard | |
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| Information Discle | osure Statement | CD, Nu | mber of | | <u> </u> | | |
| Certified Copy of Priority Document(s) Rema | | Rema | The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed. | | | | |
| Response to Miss Incomplete Applie | | | | , | | | |
| Response to Parts under 3 1.52 or 1.53 | | | | | | | |
| | SIGNA | TURE OF A | APPLICA | ANT, ATTORNEY, C | R AGENT | | |
| Firm or Individual name Harness, Dickey & Pierce, P.L. | | | Attorney Name Reg. No. | | Reg. No. | | |
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| Date November , 2003 | | | | | | | |
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| I hereby certify that the addressed to: Direct transmitted to the U.S. | tor of the U.S. Pate | ent and Irac | iemark (| Office P.O. Box 1450 | al Service a Alexandria | s first class mail in an envelope , VA 22313-1450, or facsimile | |
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PATENT

IN THE LINLE STATES PATENT AND TRADEMARK OFFICE

Application No.:

10/643,673

Filing Date:

August 19, 2003

Applicant:

Hyon et al.

Group Art Unit:

3864

Title:

Ultra High Molecular Weight Polyethylene Molded Article For

Artificial Joints and Method of Preparing The Same

Attorney Docket:

1736-000001/REC

Director of the United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. <u>LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION</u>

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

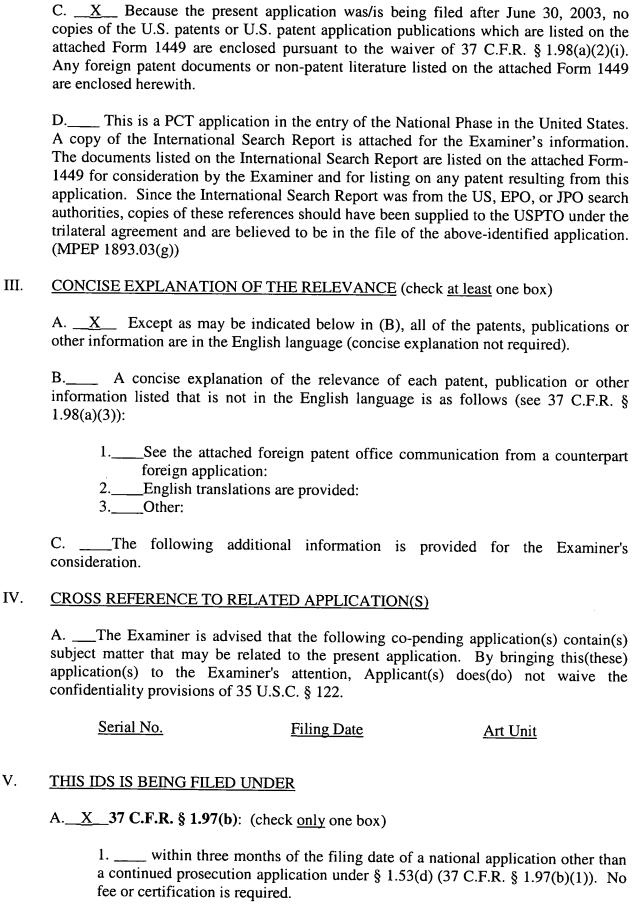
II. <u>COPIES</u>

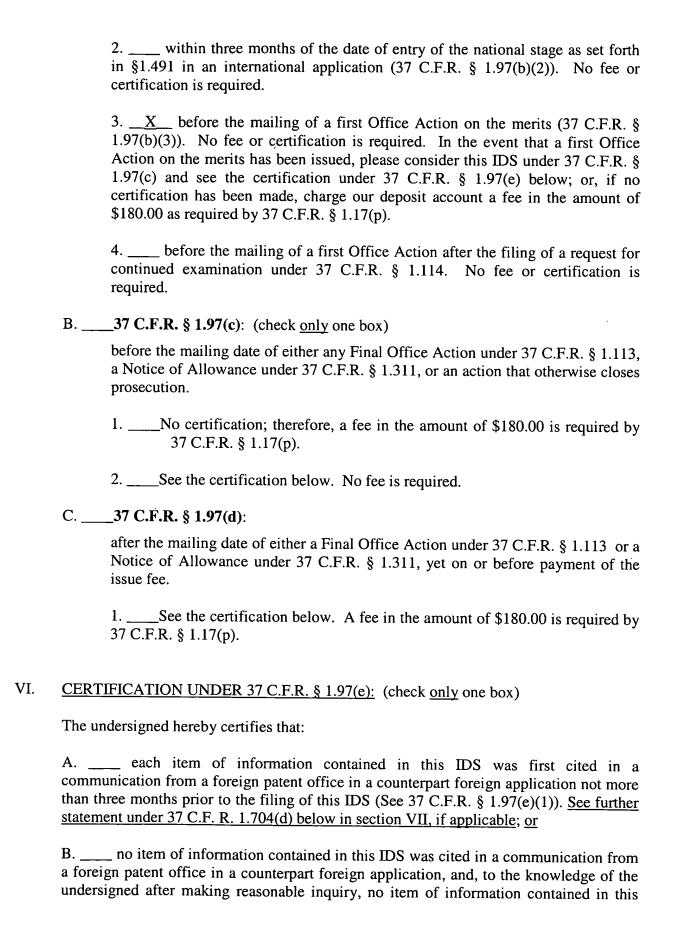
A.____ Submitted herewith is a legible copy of (i) each U.S. patent application publication and U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; (iii) for each cited pending U.S. application, the application specification including the claims, and any drawing of the application which caused it to be listed including the claims directed to that portion; and (iv) all other information or that portion which caused it to be listed.

B. X Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

<u>U.S. Serial Number</u> 10/141,374

U.S. Filing Date May 8, 2002





Serial No. 10/643,673 Page 3

IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. ____Some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 CFR 1.704(d)

The undersigned hereby states that:

each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

- A. ____ A check in the amount of \$180.00 is enclosed for the above-identified fee.
- B. ____Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

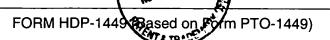
Respectfully submitted,

Dated: 19 November 2003

David L. Suter Reg. No.30,692

HARNESS, DICKEY & PIERCE, P.L.C. P.O. Box 828 Bloomfield Hills, Michigan 48303 (248) 641-1600

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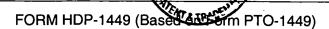
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Sheet 1 of 6

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| Hyon et al. | | | |
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| August 19, 2003 | 3864 | | |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|------------------------|--------------------|------------|--------------------|--------------------|---------------------------------|
| Ref. Desig. | Examiner's Initials | Document Number | Date | Name | Class/ Subclass | (If appropriate) Filing Date |
| 1. | | 3,886,056* | 05/27/1975 | Kitamaru et al. | | |
| 2. | | 4,224,696* | 09/30/1980 | Murray et al. | | |
| 3. | | 4,587,163* | 05/6/1986 | Zachariades | | |
| 4. | | 4,636,340* | 01/13/1987 | Itaba et al. | | |
| 5. | | 4,655,769* | 4/7/1987 | Zachariades | | |
| 6. | | 4,747,990* | 5/31/1988 | Gaussens et al. | | |
| 7. | | 5,030,402* | 7/9/1991 | Zachariades | | |
| 8. | | 5,030,487* | 7/9/1991 | Rosenzweig | | |
| 9. | | 5,066,755* | 11/19/1991 | Lemstra | | |
| 10. | | 5,130,376* | 7/14/1992 | Shih | | |
| 11. | | 5,276,079* | 1/4/1994 | Duan et al. | | |
| 12. | | 5,358,529* | 10/25/1994 | Davidson | | |
| 13. | | 5,405,393* | 4/11/1995 | Falkenstrom | | |
| 14. | | 5,428,079* | 6/27/1995 | Bastiaansen et al. | | |
| 15. | | 5,728,748* | 3/17/1998 | Sun et al. | | |
| 16. | | 2,948,666 | 8/9/1960 | Lawton | | |
| 17. | | 3,362,897 | 1/9/1968 | Lawton | | |
| 18. | | 3,956,253 | 5/11/1976 | Braun | | |
| 19. | | 4,055,862 | 11/1/1977 | Farling | | |
| 20. | | 4,171,338 | 10/16/1979 | Mason | | |
| 21. | | 4,281,420 | 8/4/1981 | Raab | | |

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| Hyon et al. | |
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| August 19, 2003 | 3864 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|------------------------|--------------------|------------|----------------------|--------------------|---------------------------------|
| Ref. Desig. | Examiner's Initials | Document Number | Date | Name | Class/ Subclass | (If appropriate) Filing Date |
| 22. | | 4,582,656 | 4/15/1986 | Hoffman | | |
| 23. | | 5,200,439 | 4/6/1993 | Asanuma | | |
| 24. | | 5,210,130 | 5/11/1993 | Howard, Jr. | | |
| 25. | | 5,414,049 | 5/9/1995 | Sun et al. | | |
| 26. | | 5,439,949 | 8/8/1995 | Lucas et al. | | |
| 27. | | 5,449,745 | 9/12/1995 | Sun et al. | | |
| 28. | | 5,505,900 | 4/9/1996 | Suwanda et al. | | |
| 29. | | 5,543,471 | 8/6/1996 | Sun et al. | | |
| 30. | | 5,552,104 | 9/3/1996 | DeNicola, Jr. et al. | | |
| 31. | | 5,577,368 | 11/26/1996 | Hamilton et al. | | |
| 32. | | 5,650,485 | 7/22/1997 | Sun et al. | | |
| 33. | | 5,879,400 | 3/9/1999 | Merrill et al. | | |
| 34. | | 6,017,975 | 1/25/2000 | Saum et al. | | |
| 35. | | 6,165,220 | 12/26/2000 | McKellop et al. | | |
| 36. | | 6,174,934 | 1/16/2001 | Sun et al. | | |
| 37. | | 6,184,265 B1 | 2/6/2001 | Hamilton et al. | | |
| 38. | | 6,228,900 B1 | 5/8/2001 | Shen et al. | | |
| 39. | | 6,281,264 B1 | 8/28/2001 | Salovey et al. | | |
| 40. | | 6,365,089 B1 | 4/2/2002 | Krebs et al. | | |
| 41. | | 6,458,727 B1 | 10/1/2002 | Jones et al. | | |

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| ATTORNEY DOCKET NO. | SERIAL NO. |
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| 1736-000001/REC | 10/643,673 |
| APPLICANT | |
| Hyon et al. | |
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| August 19, 2003 | 3864 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|------------------------|--------------------|----------|------------------|--------------------|---------------------------------|
| Ref. Desig. | Examiner's Initials | Document Number | Date | Name | Class/ Subclass | (If appropriate) Filing Date |
| 42. | | 2002/0125614 A1 | 09/12/02 | King et al. | | |
| 43. | | 2002/0037944 A1 | 03/28/02 | Shen et al. | | |
| 44. | | 2003/0119935 A1 | 06/26/03 | Merrill et al. | | |
| 45. | | 6,494,917 B1 | 12/17/02 | McKellop et al. | | |
| 46. | | 6,355,215 B1 | 03/12/02 | Poggie et al. | | |
| 47. | , | 2002/0107300 A1 | 08/08/02 | Saum et al. | | |
| 48. | | 2002/0161438 A1 | 10/31/02 | Scott et al. | | |
| 49. | | 2003/0045603 A1 | 03/06/03 | Salovey et al. | | |
| 50. | | 2003/0130743 A1 | 07/10/03 | Scott et al. | | |
| 51. | | 2003/0149125 A1 | 08/07/03 | Muratoglu et al. | | |
| 52. | | 6,048,480 | 04/11/00 | Doyle | | |
| 53. | | 6,146,426 | 11/14/00 | Doyle | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|------------------------|--------------------|------------|---------|--------------------|--------------------|-------------|
| Ref. Desig. | Examiner's Initials | Document Number | Date | Country | Class/ Subclass | Translation Yes | n No |
| 1. | | JP 57-211347 | 12/25/1982 | Japan | | Х | |
| 2. | | JP 91 22222 | 5/13/1997 | Japan | | Abstract | |
| 3. | | WO 95/06148* | 3/2/1995 | PCT | | | |
| 4. | | WO 98/01085 | 1/15/1998 | PCT | | | |
| 5. | | JP 62 243634 | 10/24/1987 | Japan | | Abstract | |

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| 1736-000001/REC | 10/643,673 |
| APPLICANT | |
| Hyon et al. | |
| FILING DATE | GROUP |
| August 19, 2003 | 3864 |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|------------------------|--------------------|-----------|---------|--------------------|--------------------|----|
| Ref. Desig. | Examiner's Initials | Document Number | Date | Country | Class/ Subclass | Translation Yes | No |
| 6. | | JP 4-198201 | 7/17/1992 | Japan | | Abstract | |
| 7. | | EP 0 729 981 A1 | 9/4/1996 | Europe | | | |
| 8. | | JP 5-507748 | 11/4/1993 | Japan | | Abstract | |
| 9. | | JP 2-175137 | 7/6/1990 | Japan | | Abstract | |

| OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.) | | | |
|--|------------------------|---|--|
| Ref. Desig. | Examiner's Initials | | |
| 1. | | Choudhury et al., "The effects of irradiation and ageing on the abrasive wear resistance of ultra high molecular weight polyethylene," Wear 203-204 (1997), pp. 335-340. | |
| 2. | | International Search Report, PCT/US97/11947 - included in WO 98/01085. | |
| 3. | | Kang et al., "The Radiation Chemistry of Polyethylene. IX. Temperature Coefficient of Cross-Linking and Other Effects," Journal of the American Chemical Society, Vol. 89:9, April 26, 1967, pp. 1980-1986. | |
| 4. | | Kitamura, R. et al., "The Properties of Transparent Film Made from Linear Polyethylene By Irradiation Cross-Linking," Macromolecules, vol. 6, 1973, pp. 337-343.* | |
| 5. | | Kitamura, R. et al., Structure and Properties of Lightly Crosslinked Crystalline Polymers Crystallized or Processed under Molecular Orientation, Journal of Polymer Science: Macromolecular Reviews, vol. 14, 1979, pp. 207-264.* | |
| 6. | | Kitamuru, R. et al., "Size and Orientation of Cristallites in Lightly Cross-linked Polyethylene, Crystallized from the Melt Under Unaxial Compression," DieMakromoekulare Chemie, vol. 175, 1974, pp. 255-275.* | |
| 7. | | O'Neill et al., "The distribution of oxidation products in irradiated ultra-high molecular weight polyethylene," Polymer Degradation and Stability (Feb. 1995), pp. 239-244. | |

| Examiner: | |
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FORM HDP-1449 (Based of Form PTO-1449)

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| ATTORNEY DOCKET NO. | SERIAL NO. | |
|---------------------|------------|--|
| 1736-000001/REC | 10/643,673 | |
| APPLICANT | | |
| Hyon et al. | | |
| FILING DATE | GROUP | |
| August 19, 2003 | 3864 | |

| OTHE | R DOCUME | NTS (including Author, Title, Date, Pertinent Pages, etc.) |
|----------------|---------------------|--|
| Ref. Desig. | Examiner's Initials | |
| 8. | | Oonishi et al., "Effect of cross-linkage by gamma radiation in heavy doses to low wear polyethylene in total hip prostheses," Journal of Materials Science: Materials in Medicine 7 (1996), pp. 753-763. |
| 9. | | Oonishi et al., "The optimum dose of gamma radiation-heavy doses to low wear polyethylene in total hip prostheses," Journal of Materials Science: Materials in Medicine 8 (1997), pp. 11-18. |
| 10. | | Polymer Society, Polymer Functional Material Series-Medical Treatment Functional Material, Vol. 9, November 20, 1990, pp. 165-166. |
| 11. | | Polymer Society, Polymer New Material One Point-Medical Polymer Material, Vol. 20, February 20, 1989, pp. 45-46. |
| 12. | | Premnath, "Gamma sterilization of UHMWPE articular implants: an analysis of the oxidation problem," Biomaterials, Vol. 17 No. 18 (1996), pp. 1741-1753. |
| 13. | | Sun et al., "Development of an Accelerated Aging Method For Evaluation of Long-term Irradiation Effects on UHMWPE Implants," (1996), Howmedia Inc., Pfizer Hospital Products Group, pp. 969-970. |
| 14. | | Supplementary European Search Report, EP 95931434, December 28, 1998 - corresponds to EP 0729981. |
| 15. | | The American Academy of Orthopaedic Surgeons, "Polyethylene: The Past, Present and Future," 1999 Annual Meeting - Scientific Program, February 5, 1999, www.aaos.org/wordhtml/anmett99/sciprog/g.htm (20 pages). |
| 16. | | The American Academy of Orthopaedic Surgeons, "Researchers get awards for orthopaedic research," News Release, March 19, 1998, www.aaos.org/wordhtml/press/98press/kappa.htm (4 pages). |
| 17. | | The American Academy of Orthopaedic Surgeons, "Researchers to get Kappa Delta awards for achievements," Academy News, March 19, 1998, www.aaos.org/wordhtml/98news/kappa.htm (3 pages). |
| 18. | | Tribology Laboratory information sheet and curriculum vitaes for Drs. McKellop and Shen, www.orthohospital.org/research/Tribology Lab (5 pages). |

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| Examiner: | Deta Canaldana I |
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|---------------------|------------|--|
| 1736-000001/REC | 10/643,673 | |
| APPLICANT | | |
| Hyon et al. | | |
| FILING DATE | GROUP | |
| August 19, 2003 | 3864 | |

| OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.) | | | |
|--|------------------------|---|--|
| Ref. Desig. | Examiner's Initials | | |
| 19. | | Wilson et al., "Proton Modification of Ultra High Molecular Weight Polyethylene to Promote Crosslinking for Enhanced Chemical and Physical Properties," Materials Research Society Symposium Proceedings, Vol. 396 (1995), pp. 311-316. | |

^{*} Indicates previously cited in original U.S. Patent 6,168,626.

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| Examiner: | Data Camaidanada |
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